Biotech Injectable Drugs: Clinical Applications and Financial Effects

Biotechnology-derived injectable medications raise complex issues with respect to access and administration for both manufacturers and payers. In addition, biotech injectables rarely fit within traditional prescription drug benefit design structures, thereby creating inequities in reimbursement and access that can undermine a health benefit plan's goals.

Benefit-design changes focusing on short-term solutions can exacerbate such situations. Employers, insurers, and managed care organizations need to consider innovative benefit-plan designs to effectively address issues that are associated with biotech medications.

Actuarial models, such as the Reimbursement model described in this article, can help to provide the options analyses and decision-making support that are required.

First of two parts.

BY F. RANDY VOGENBERG, RPH, PHD, AND COLEEN YOUNG, FSA

Over the past decade, medical research has yielded medications and treatments that, only a few years ago, would have been considered miracles of technology. Second- and third-generation antibiotics and select chemotherapeutic and neurologic agents represent steady, progressive advances against common human maladies. Until recently, HIV-positive individuals or those with cancer or certain immune-system disorders could anticipate a predictable decline of health and then death; now, such patients can be treated with pharmaceutical therapies that allow them to continue to pursue productive and satisfying lives.

Biotechnology-derived medications are the leading edge of medical treatment today. Biopharmaceuticals act at a specific site or cell protein that is pertinent to the prevention, treatment, or cure of disease or injury. Biotech injectable medications primarily are used to treat low-prevalence, high-cost diseases for which previous treatments were more invasive, risky, and/or costly, or unavailable. Examples include:

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- Etanercept (Enbrel), adalimumab (Humira), and infliximab (Remicade) for rheumatoid arthritis
- Interferon ß-1b (Betaseron) or interferon ß-1a (Avonex) and glatiramer acetate (Copaxone) for relapsing-remitting multiple sclerosis
- Filgrastim (Neupogen) for chemotherapy-induced neutropenia

Today, for physicians and their patients, biotech injectable medications have become valuable tools that may improve outcomes and quality of life for patients with previously untreatable conditions, lessen the adverse effects of current therapy, and halt or slow disease progression.

In practical terms, this means reducing pain and discomfort, avoiding hospitalization, and continuing with normal routines, including work. As with other important shifts in medical technology, treatment with biotech injectables has yielded significant benefits to the patient and others (including employers) who are affected by the patient's health status and abilities.

A study by the Medical Research Center for Arthritis at the University of California–San Francisco found that, among participants employed at diagnosis, those taking etanercept for rheumatoid arthritis were better able to remain at work (20 percent more than the control group) and were able to work 7.4 more hours per week than the control group (Yelin 2003).

The dramatic and positive impact of biotech injectable medications on patient health has ensured their increased use in the future.

EFFECT ON HEALTH PLANS

Biotech injectable medications have become a cost driver within the prescription drug benefit, a phenomenon affected by both volume and unit cost.

The number of available biotech therapies is expanding rapidly, with the average 30-day prescription costing in excess of $1,000. Further, significant increases are expected in both volume and cost. Biotech industry sales for human therapeutic agents are projected to rise 20 to 40 percent per year (Consulting Resources 2001).

While biotech injectable medications have extremely high annual costs relative to other prescription medications, they represent a comparatively small share — less than 5 percent — of total prescription drug expenses (Consulting Resources 2001). Nonetheless, with prescription drug cost increases outpacing health plan cost increases, and with biotech injectables making up an increasing portion of prescription drug costs, the cost impact of biotech injectable medications is, understandably, receiving attention (Figure 1).

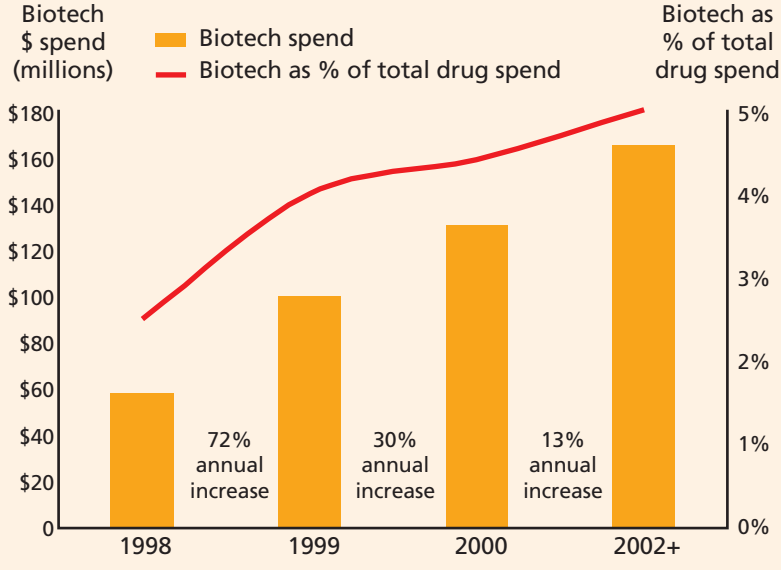
The new, more complex access and administration issues that biotech drugs raise are due primarily to the injectable method of delivery for the great majority of these agents. While a physician in a clinical or hospital setting historically has administered injectable medications, many biotech injectables can be administered by the patient at home.

Thus, patients may gain access to their medications through various sources, including their physicians, community pharmacies, or mail order pharmacies. As a result, some claims for injectable medications are paid under the patient's medical benefit plan (typically, those administered by a physician in a healthcare setting), while others are covered under the patient's prescription drug plan. Because medical and prescription drug benefit plans feature different reimbursement mechanisms, inconsistencies relative to payments and patient cost-sharing are common.

Other aspects of the employer's health plan also are affected. Claims processing is complicated by the inconsistent approach to coverage. Disease and utilization management programs are not equipped to handle what is, under current plan designs, an atypical situation. Purchasing efficiencies are mitigated through the use of multiple unmanaged sources.

Perhaps most critically, data capture is compromised. Without consistent coverage of benefits and capture of claims and services data, an employer cannot assess the quality, value, and cost-effectiveness of biotech injectable medications, particularly as they relate to other covered healthcare services.

FIGURE 1 Fast-growing biotech expenditures



SOURCES: CAREMARK BIOTECH SAMPLE CLIENT DATABASE 2002, AON 2003 ESTIMATES

LIMITATIONS OF CURRENT DRUG BENEFIT DESIGNS

Current prescription drug benefit designs were intended for medications of low and moderate cost that can be administered without assistance. In contrast, medical benefit plan designs were intended to compensate physicians for professional services related to the administration of injectable medications, as well as to reimburse them for the cost of those medications. Specific medication costs are not identified and, for the patient, coverage typically involves a single co-

TABLE 1 Overview of actuarial models[1]

Reimbursement model: Demonstrates the financial impact of varying benefit design and/or provider reimbursement on key stakeholders (employers, employees, and providers) for costs associated with individual injectables.

Aggregate model: Demonstrates the financial impact of varying benefit design on key stakeholders (employers and employees) for costs associated with the top 15 injectables (grouped into five disease categories) for a group of plan members.

Total Cost of Care model: Demonstrates the benefit design impact on optimal usage of injectables (for each disease category and in aggregate) and the resulting financial effect on employers and employees — for injectable costs, overall healthcare costs, and productivity costs.

[1] Reimbursement model © 2003 Aon Consulting.
Aggregate model © 2003 Aon Consulting.
Total Cost of Care model © 2004 Aon Consulting.

payment for each physician-office visit.

Because biotechnology therapies do not fit neatly within traditional benefit design structures, there is confusion regarding appropriate and equitable physician reimbursement for professional administration services and medication costs.

Furthermore, increasing patient cost-sharing under both prescription drug and medical plans has affected access to affordable care. The high cost of biotech injectable medications (usually combined with other expenses that are associated with treating a chronic condition) often requires significant out-of-pocket expenditures. For some patients, this may result in either restricting the care they can afford to receive, or in inappropriate and inefficient use of medical technologies and treatments.

The value and efficacy of biotechnology medications ensure their increased use in the future. Issues relating to access and reimbursement will intensify as these agents continue to represent a rapidly growing portion of all medications.

CONSTITUENTS' PERSPECTIVE

As a significant cost of doing business — and as a significant tool in attracting and retaining a productive, quality workforce — employer healthcare benefits are structured to meet specific goals: provide appropriate, cost-effective coverage for healthcare services; control costs; and maintain employee productivity and satisfaction.

To support their employer clients in achieving these goals — and thereby retain their membership — MCOs or insurers must provide attractive, cost-effective options for employers and their employees, and must ensure provider satisfaction with reimbursement levels and administrative efficiency.

Nevertheless, as the effects of biotech injectable medications on the various components of health benefit plans grow, the ability of employers and MCOs to achieve these goals is slowly being eroded.

By inadvertently limiting access and reimbursement, plan designs can have the unintended effect of increasing overall costs. Also by default, existing plan designs encourage underutilization of biotechnology medications, which have the potential to improve patient quality of life, reduce overall medical expenses, and maximize employee productivity and performance. To address such consequences, employers and MCOs need to consider a number of design elements to enhance their benefit plans.

The key to designing the appropriate coverage is to create appropriate incentives. Neither physicians nor patients should have an incentive to avoid utilizing treatment options that are cost-effective and/or that can significantly improve patient health or patient quality of life. For biotech injectable medications meeting these criteria, at least the following questions should be addressed:

- Under what umbrella (e.g., medical or prescription drugs) is coverage for biotech medications provided?
- What is the effect of the existing provider reimbursement mechanism on utilization of these medications?

- What incentives does existing coverage create for utilization of these medications via different provider types/settings?
- What is the effect of existing patient cost-sharing features on utilization of these medications?
- Would changes in any of the above change utilization, cost, or quality of life?

Clearly, a better approach to the management of all pharmaceutical products in health benefit programs is needed. Accepting the limitations of the status quo, adopting short-term solutions, or patching in partial "fixes" ultimately creates inequities, problems, and confusion. Employers and MCOs find that, over time, the difference between what is intended — appropriate and cost-effective coverage, managed costs, and employee productivity and satisfaction — and what actually is delivered becomes more pronounced.

A thorough analysis of these issues, while clearly a complex undertaking, is key in identifying those elements of benefit design that must be addressed to ensure appropriate, cost-effective coverage and reimbursement for biotech injectable medications. An important first step in better defining the issues and determining the optimal approach would be to conduct an extensive literature review and evidence-based analysis.

LITERATURE FINDINGS

Because of the complexity of the current situation with respect to coverage, financing, access, reimbursement, and administration of biotech injectable medications, we conducted an extensive multi-index literature review. The purpose was to gain a thorough understanding of the existing situation and to determine the best approach with respect to further analyses. The following are among the key finds of the literature review:

- There are more than 80 FDA-approved biotech medications and vaccines on the market in the United States, with another 350+ in human trials (Consulting Resources 2001). Ninety-nine percent of these agents are administered via injection (Sirois 2002).
- Biotech injectable medications are costly, averaging $1,170 for a 30-day prescription. Yet, they represent only about 3 percent of total outpatient drug spending (Wilson 2002).

TABLE 2 Examples of key findings using the reimbursement model

With respect to changes in medical plan benefits:

- Dramatic changes in patient cost-sharing (coinsurance, out-of-pocket maximums) can have a huge negative cost impact on patients with chronic illnesses while producing minimal savings to employers (Figure 2).
- Even these minimal employer savings would be at least partially offset by increased overall healthcare and productivity costs associated with deterring appropriate utilization. (This will be addressed further in the Aggregate and Total Cost of Care models, forthcoming in part 2 of this series.

With respect to changes in prescription drug benefits:

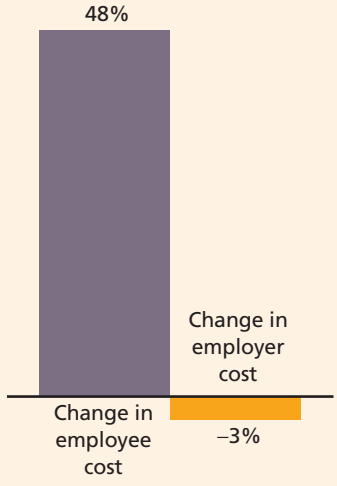
- Raising copayments, even to very high levels, is unlikely to provide meaningful cost control for injectables (Figure 3a).
- The introduction of annual benefit maximums can render other benefit design features (e.g., coinsurance) meaningless and/or place an unintended burden on patients (Figure 3b).

With respect to changes in plan of coverage and/or provider reimbursement for physician-administered injectables:

- Provider reimbursement would decrease dramatically if coverage was moved to the prescription drug plan; little of this cost decrease would accrue to the employer, however (Figure 4, Alt. 1, page 37).
- Employers may decrease their cost further by continuing to provide coverage under the medical plan but also by pressing MCOs to reduce physician reimbursement for injectables, providing a middle-ground solution (Figure 4, Alt. 2, page 37).

FIGURE 2 Medical benefit scenario

Significantly increased patient cost-sharing relative to status quo

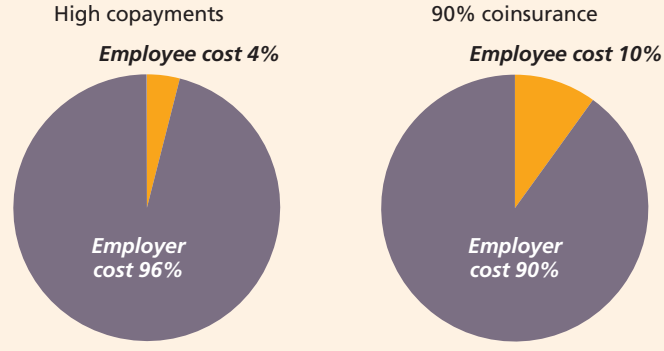


SOURCE: AON CONSULTING

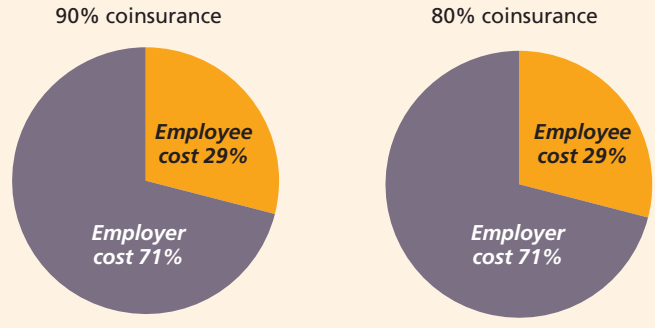
- The use of biotech injectable medications is expected to increase significantly, with industry sales projected to rise 20 to 40 percent per year. Biotech sales are expected to total $27 billion per year by 2008 (Consulting Resources 2001).
- Traditionally, injectables have been covered under the medical benefit plan, with utilization and purchase controls at the physician level. Data capture, however, often does not include details about specific medications administered by the physician.
- As the use of self-administered biotech medications has become more commonplace, multiple providers — including home infusion companies, mail order pharmacy benefit managers, retail pharmacies, and specialty pharmacies — have emerged into the marketplace. As a result, it has become increasingly difficult to gain control over the cost and management of these products.
- Coverage for self-administered biotech injectable medications is typically provided under the patient's prescription drug plan. Coverage for physician-administered injectables, however, is still generally provided under the patient's medical plan. The resultant differences in coverage and reimbursement are further distorted by varying Medicare reimbursement schemes.
- These inconsistencies in coverage for biotech injectable medications affect employer health plans in the areas of cost, utilization, data capture, disease management, and overall plan management.
- In response, health plans are adopting stopgap measures, including moving biotech injectable medications to the prescription drug plan, increasing member liability through additional copayments and out-of-pocket maximums, and introducing specialty pharmacy carve-out plans.
- Any given change to the ben-

FIGURE 3 Prescription drug benefit scenarios: stakeholder cost impact

A. No annual maximum



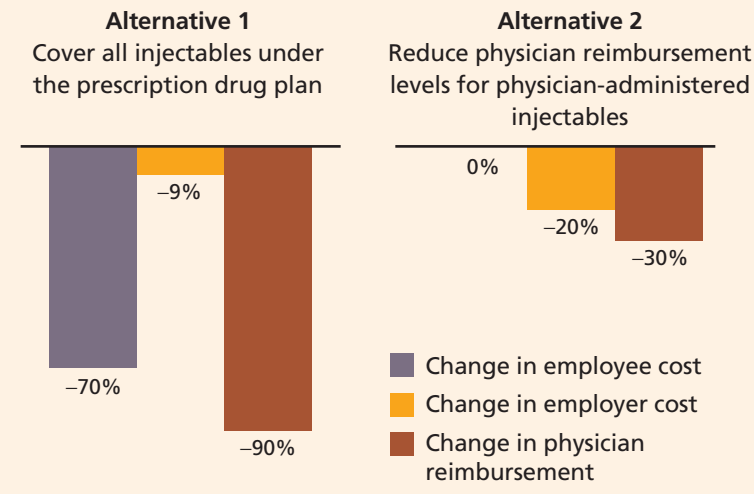
B. $10,000 annual maximum



SOURCE: AON CONSULTING

FIGURE 4 Coverage of physician-administered injectable medications

Stakeholder cost impact relative to status quo



SOURCE: AON CONSULTING

efit plan affects the interests of many different stakeholder constituencies — employers, providers, patients, health plans, insurance carriers, PBMs — and may result in "winners" and "losers" in terms of cost and utilization.

To summarize, biotech injectable medications present a number of issues affecting medical and prescription drug benefit plans. These include inconsistencies in coverage and reimbursement, effects on efficient and effective utilization, complexities in plan administration and claims processing, difficulties in data capture and plan management, and obstacles to determining or demonstrating value.

The literature review confirmed employers' and MCOs' need to address these issues by modifying existing benefit designs to provide more effective coverage of biotech injectable medications. This will necessitate changes to both the medical and prescription benefit plans.

Determining what changes to benefit design will ensure appropriate coverage for and usage of biotech injectable medications necessitates a detailed look at a number of plan features and data points. Further complicating this analysis is the effect that these elements have on one another as potential design changes are contemplated. To date, employers and MCOs have lacked the tools needed to support these complex design and decision-making processes.

A series of three actuarial models, incorporating a broad range of critical assumptions and considerations, can allow employers and MCOs to test and understand the implications of different design approaches — not only on the cost of biotech injectable medications, but also on overall healthcare costs and productivity. The first of these models is discussed in detail herein.

ACTUARIAL MODELING

The goal of the actuarial models is to support informed decision-making regarding the most appropriate benefit-design modifications needed to address the issues raised by biotech injectable medications. To that end, the three actuarial models described in Table 1, on page 35, can be used to evaluate issues from an increasingly macroeconomic perspective.

Although the Total Cost of Care model may be viewed as an end product by some users, others — because of its big-picture perspective — may find that the Reimbursement and Aggregate models provide all the key results needed to make informed decisions.

Reimbursement model

The Reimbursement model is designed with several goals in mind:

- It demonstrates the implications of the status quo for key stakeholders, as determined through the literature review.
- It allows users to evaluate alternatives to the status quo with respect to benefit design and provider reimbursement.
- Employers can evaluate tradeoffs associated with aggregate cost control versus ensuring employee satisfaction.
- MCOs can evaluate tradeoffs associated with providing attractive options to employers for more cost-effective coverage versus ensuring provider satisfaction.

The reimbursement model user is able to select one of the top injectable medications (from a list of approximately 20) and then analyze

the effect of user-driven assumptions regarding provider reimbursement and benefit design. Specifically, users can vary the following assumptions:

- Plan of coverage (medical or prescription drug)
- Compensation levels for various types of providers and for injection administration versus the injectable medication
- Utilization breakdown among types of providers
- Benefit-design assumptions for both medical and prescription drug plans (e.g., copayments, coinsurance, out-of-pocket limits, and annual benefit maximums)

The model can be used to evaluate up to three alternative scenarios at once and compare results to the status quo scenario. The results provided for each alternative include: annual employee and employer costs for the selected injectable drug, and percent of cost borne by each; percent change in employee and employer cost relative to the status quo (in total and by provider type); and change in provider reimbursement relative to the status quo (in total and by provider type).

As the examples in Table 2 (page 36) illustrate, the reimbursement model is particularly useful for analyzing consequences that are unintended; because of the unique issues associated with biotech injectable medications, benefit design changes often produce counterintuitive results in this area.

CONCLUSION

In this article, the first of two in this series, the clinical and economic impact of biotech injectable medications was exposed to generate new thinking about traditional prescription drug benefit coverage plans. Employers, insurers, and MCOs must find and use an innovative and proactive approach — unlike traditional methods of handling oral medications — to address the coverage, financing, access, reimbursement, and administration issues associated with biotech injectable medications.

The biotech industry will experience significant increases in medication sales through the end of this decade, owing to the value of these agents with respect to improving clinical outcomes. This will occur despite limitations in access and reimbursement as biotech medications continue to represent a growing percentage of all medications. Therefore, the financial implications for their use must be examined in a way that establishes their overall value in the healthcare marketplace. As a result, the understanding and evaluation of clinical and financial outcomes will be an increasingly necessary part of the biotech healthcare landscape.

By actuarially modeling specific plan-design changes and detailing the effect on all stakeholder constituencies, employers and MCOs can identify the optimum plan designs for their respective organizations as well as for employees or members. As a result, more objective, rational benefit plan decisions that benefit all stakeholders can be made. Manufacturers must also recognize this and the various financial effects a new medication may have on the marketplace beyond just the clinical implications for improved patient outcomes.

Rather than adopting partial "fixes," all stakeholders should seek to create value and align benefit plans with their core goals. To do so, they must thoroughly understand the implications of plan design changes on costs, reimbursements, and utilization before implementing those changes. A series of actuarial models to be explored in the next issue of BIOTECHNOLOGY HEALTHCARE can provide the decision-making support that is required but lacking in the marketplace to value biotech injectable medications appropriately.

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In the next issue of BIOTECHNOLOGY HEALTHCARE, authors Vogenberg, Young, and Debbie Liebeskind, FSA, detail the Aggregate and Total Cost of Care models.